think 80 years testing is more than sufficient, and I would remind the Panel that we're supposed to be looking at reasonable assurances of safety and efficacy and we're also supposed to be looking at least burdensome, what is the least burdensome way to satisfy ourselves that this product is safe and effective. And you have a product that has 17 years of experience in Europe. We have seen some failures, but, as Dr. Besser mentioned, none of them seem to have been related to the devices. I just don't understand why you would want to add this extra burden to the company.

CHAIRPERSON YASZEMSKI: Thank you, Ms. Maher. Ms. Luckner? Thank you. Let's vote. Dr. Diaz? The vote is for a motion to require post-approval study both for wear data to 50 million cycles and to study coupled motion, flexion-extension with lateral bending.

DR. DIAZ: I disagree.

CHAIRPERSON YASZEMSKI: Thank you, Dr. Diaz. Dr. Mabrey?

DR. MABREY: On this motion I will

disagree.

CHAIRPERSON YASZEMSKI: Thank you, Dr. Mabrey. Dr. Finnegan?

DR. FINNEGAN: I don't think I have a vote, but I agree.

CHAIRPERSON YASZEMSKI: Thank you. Dr. Kim?

DR. KIM: I disagree.

CHAIRPERSON YASZEMSKI: Thank you. Dr. Naidu?

DR. NAIDU: I disagree.

CHAIRPERSON YASZEMSKI: Thank you. Dr. Kirkpatrick?

DR. KIRKPATRICK: I agree.

CHAIRPERSON YASZEMSKI: Thank you. Dr. Blumenstein?

DR. BLUMENSTEIN: Disagree.

CHAIRPERSON YASZEMSKI: Thank you. Dr. Besser?

DR. BESSER: Disagree.

CHAIRPERSON YASZEMSKI: Thank you. This motion does not pass. I will ask now if anybody would

like to offer additional motions for conditions to be included. Dr. Besser?

DR. BESSER: I would like to move that the post-marketing study be done looking at the multiple modes of wear in the prosthesis, I think, 10 million cycles with both flexion-extension and lateral bending at the same time.

CHAIRPERSON YASZEMSKI: Thank you, Dr. Besser. Do I have a second for this motion?

DR. KIRKPATRICK: Second.

CHAIRPERSON YASZEMSKI: Thank you, Dr. Kirkpatrick. Discussion, Dr. Diaz?

DR. DIAZ: Well, I think really that's the part that we haven't seen that is critical to the evaluation. We have seen pretty much all other mechanical ways of evaluating this particular device. I think that would compliment it well.

CHAIRPERSON YASZEMSKI: Thank you, Dr. Diaz. Dr. Mabrey?

DR. MABREY: No comment.

CHAIRPERSON YASZEMSKI: No comment? Dr. Finnegan?

DR. FINNEGAN: No comment.

CHAIRPERSON YASZEMSKI: Thank you. Dr. Kim?

DR. KIM: No comment.

CHAIRPERSON YASZEMSKI: Thank you. Dr. Naidu?

DR. NAIDU: I think that's a reasonable addition.

CHAIRPERSON YASZEMSKI: Thank you. Dr. Kirkpatrick?

DR. KIRKPATRICK: No further comment.

CHAIRPERSON YASZEMSKI: Thank you. Dr. Blumenstein?

DR. BLUMENSTEIN: No comment.

CHAIRPERSON YASZEMSKI: Thank you. Dr. Besser, you made the motion. Any additional comments?

DR. BESSER: No.

CHAIRPERSON YASZEMSKI: Thank you. Ms. Maher?

MS. MAHER: I'm okay.

CHAIRPERSON YASZEMSKI: Thank you. Ms. Luckner?

MS. LUCKNER: I'm okay.

CHAIRPERSON YASZEMSKI: Okay. We have a motion to have a post-approval study of flexion-extension in-vitro coupled with lateral bending to 10 million cycles. We'll vote on that motion. Dr. Diaz?

DR. DIAZ: I agree.

CHAIRPERSON YASZEMSKI: Dr. Mabrey?

DR. MABREY: I agree.

CHAIRPERSON YASZEMSKI: Dr. Finnegan?

DR. FINNEGAN: I agree.

CHAIRPERSON YASZEMSKI: Dr. Kim?

DR. KIM: I agree.

CHAIRPERSON YASZEMSKI: Dr. Naidu?

DR. NAIDU: I agree.

CHAIRPERSON YASZEMSKI: Dr. Kirkpatrick?

DR. KIRKPATRICK: Agree.

CHAIRPERSON YASZEMSKI: Dr. Blumenstein?

DR. BLUMENSTEIN: Agree.

CHAIRPERSON YASZEMSKI: Dr. Besser?

DR. BESSER: Agree.

CHAIRPERSON YASZEMSKI: All right. This motion passes. We now have three conditions to the

motion for approval with conditions. Do I have any motions for additional conditions? Dr. Finnegan?

DR. FINNEGAN: Yes, I would think that mandatory training of surgeons would be an additional condition.

CHAIRPERSON YASZEMSKI: Okay. Do I have a second for this motion?

DR. DIAZ: Second.

CHAIRPERSON YASZEMSKI: Dr. Diaz. Discussion, Dr. Diaz?

DR. DIAZ: I think probably of all the things we do in spine surgery, this is going to be the one that will require the most supervision, monitoring and critical analysis of the ability of the individual to do this procedure. Unfortunately, many of these surgical interventions in the spine have been released relatively freely and this particular device, I think, has some very peculiar functional components that will require a very detailed evaluation not only of the implantation and its technique, but the surgeon as well. So I think it is critical to have that as a requirement.

CHAIRPERSON YASZEMSKI: Thank you, Dr. Diaz. Dr. Mabrey?

DR. MABREY: No comments.

CHAIRPERSON YASZEMSKI: Dr. Finnegan?

DR. FINNEGAN: No comments.

CHAIRPERSON YASZEMSKI: Dr. Kim?

DR. KIM: No comment.

CHAIRPERSON YASZEMSKI: Dr. Naidu?

DR. NAIDU: No comment.

CHAIRPERSON YASZEMSKI: Dr. Kirkpatrick?

DR. KIRKPATRICK: My only comment would be that it would be consistent with other products, which may have had the same kind of restriction.

CHAIRPERSON YASZEMSKI: Thank you. And when we go around, I'm going to ask Dr. Witten if she'll comment on the history of this type of requirement at FDA. Dr. Blumenstein?

DR. BLUMENSTEIN: No comment.

CHAIRPERSON YASZEMSKI: Dr. Besser?

DR. BESSER: No comment.

CHAIRPERSON YASZEMSKI: Ms. Maher?

MS. MAHER: No comment.

CHAIRPERSON YASZEMSKI: Ms. Luckner?

MS. LUCKNER: I'm very pleased to see this added as a condition. It has been a concern of mine as I have heard this whole presentation that the results are directly related to the time and the experience, and I commend the company for the thoughtfulness they have taken in planning this out from the get-go before we even brought it up. They have made provision for it, so I think that's remarkable.

CHAIRPERSON YASZEMSKI: Thanks so much. Dr. Witten, may I ask you, what is the history of this type of requirement at FDA?

DR. WITTEN: Well, we can require that the sponsor have training available, a training program available, and I think we can actually require that they distribute to people who have had training, okay, and I think we have done both.

CHAIRPERSON YASZEMSKI: Okay.

DR. WITTEN: Is the answer.

CHAIRPERSON YASZEMSKI: Thank you.

DR. WITTEN: Or neither and neither.

CHAIRPERSON YASZEMSKI: Thank you. We'll vote on this. This is to require that training be available for surgeons before they do this procedure and we'll vote for this then. Further commentary, Dr. Kirkpatrick?

DR. KIRKPATRICK: My understanding was the motion was to require training prior to distribution of the device to that individual. Is that the motion?

CHAIRPERSON YASZEMSKI: Okay. Is that the --

DR. KIRKPATRICK: Then would it imply, based upon what we just heard from Dr. Witten, that there would be certification of the individual or a graduate certificate from the training program? Is that what we're talking about?

CHAIRPERSON YASZEMSKI: May I comment? If I may comment, I think that training centers may give a certificate or a statement that a person has completed the training, but they may not certify the person as having any level of expertise in the training. They can just say what their course outline was and that the person went through that outline.

DR. KIRKPATRICK: As I understand your motion, it is to basically have somebody trained by the company to do it, trained by the company, not the company itself, but a training center approved by the company to do it.

DR. DIAZ: I don't know that the company really is the group that needs to issue that.

DR. KIRKPATRICK: Let me just say by approved training agency.

DR. DIAZ: Yes, I think that would be a better statement. What do you think?

DR. WITTEN: Well, I just want to clarify something, and then I see that Ms. Maher may have some other clarification to my clarification, but our only requirement would be on what the sponsor does. We don't have any requirements on, you know, what a hospital would allow a surgeon to do based on, you know, certain training that somebody else provided. So it's through the sponsor either providing something or ensuring that it's available.

CHAIRPERSON YASZEMSKI: Thank you.

DR. WITTEN: And it's not, you know,

having -- not engaging in having some other training occur.

CHAIRPERSON YASZEMSKI: Thank you, Dr. Witten. Ms. Maher?

MS. MAHER: Yes, I think I would like Mr. Christianson to comment on this and what they are planning, but I also would like to comment myself that I think we have to be very careful not to tell the industry that they have to certify that a doctor meets certain skills.

CHAIRPERSON YASZEMSKI: No, no, that's not what's being said at all.

MS. MAHER: Right. What I would really like to see is that we say we want training to be done and we allow the FDA and the sponsor to work out what the most appropriate form of training is and for how many years they are going to have to train, because in 10 or 15 years this could be -- hopefully, will be state of the art and nobody is going to want to have to go through an additional training course to do it. But, Bill, do you want to comment on the plans that you all have?

CHAIRPERSON YASZEMSKI: Yes, I would ask Mr. Christianson. Would you care to make a comment?

MR. CHRISTIANSON: Bill Christianson. Yes, thank you for calling me up. One of the conditions that you mentioned, Dr. Kirkpatrick, is that an individual has to be trained before they can be sold to you. You need to understand that as an industry, we sell to a hospital and so we're very happy to have a very robust training program. We're absolutely committed to having the highest quality training program and we want every single surgeon who is going to use this device to go through the program.

But honestly, that is really managed at the local level by hospital credentialing committees and we would be very happy to have those committees adopt a statement saying that you must go through the training program or you must have an experienced surgeon at your side while you're doing your cases, but we can't control an individual who buys, because we sell to an individual hospital. So we're very happy to have a condition that we have a robust training program and it has already been said, we

can't certify physicians and I don't think anybody in the Panel wants us to.

DR. KIRKPATRICK: You have pointed out exactly my concern about communication here. We need to make sure that the condition that's being sought can be done.

MR. CHRISTIANSON: We can have a robust training program.

DR. KIRKPATRICK: In other words, if UAB Hospital calls him and says we want the Charite Disc even though none of our surgeons have been trained on it, he doesn't have any authority or power to stop that disc from being sold to the hospital is what he just said.

MR. CHRISTIANSON: Well, actually, I can stop that, but once you have been trained there, I can't stop it being sold.

DR. KIRKPATRICK: Okay.

MR. CHRISTIANSON: And then your colleague.

DR. KIRKPATRICK: That's what I'm trying to clarify, because we got that you will ensure

training. Okay. You can ensure training, but only if people go there. Is there a way that FDA can require the distribution of the product only to people that have demonstrated to the distributors, I guess, or to somebody that they have had the training?

DR. WITTEN: Well, I don't really have anything to say beyond what I already said, which is we have done it both ways, you know, both having, you know, anybody who receives it to use it be trained and also requiring that training be available. And I really don't know what the logistics have been in the other circumstances.

CHAIRPERSON YASZEMSKI: Okay. Thank you, Dr. Witten. So we have had a discussion on it and we can see that, I think, Ms. Maher summed it up, that if we vote for this, the details will be worked out between the FDA and the company to the satisfaction of both, and we're just voting to make that recommendation to FDA that they enter into that discussion and see that it's accomplished to their satisfaction. So with that, we're going to vote. Dr. Diaz?

DR. DIAZ: I agree.

DR. KIRKPATRICK: Can we hear the motion again, because what you said is different than what I understood he moved.

CHAIRPERSON YASZEMSKI: Okay. The motion is that training will be made available and that the FDA will insist that the company make training available. However, at the point of requiring (A) either certification of surgeons as being adept at the technique, we have to stop, because neither the FDA nor the company can influence medical practice, and that will have to be left to the discretion of the State Licensing Boards and the Hospital Credentials Committees. That is the nature of the motion.

UNIDENTIFIED SPEAKER: That's your motion.

DR. DIAZ: I agree.

CHAIRPERSON YASZEMSKI: Agree. Dr. Mabrey?

DR. MABREY: I agree.

CHAIRPERSON YASZEMSKI: Dr. Finnegan?

DR. FINNEGAN: Agree.

CHAIRPERSON YASZEMSKI: Dr. Kim?

DR. KIM: I agree.

CHAIRPERSON YASZEMSKI: Dr. Naidu?

DR. NAIDU: I agree.

CHAIRPERSON YASZEMSKI: Dr. Kirkpatrick?

DR. KIRKPATRICK: I agree.

CHAIRPERSON YASZEMSKI: Dr. Blumenstein?

DR. BLUMENSTEIN: Agree.

CHAIRPERSON YASZEMSKI: Dr. Besser?

DR. BESSER: I agree.

CHAIRPERSON YASZEMSKI: Okay. This motion passes. We now have four conditions to the motion for approval with conditions. Do we have other motions for additional conditions? Dr. Kirkpatrick?

DR. KIRKPATRICK: Here comes Simon again. Following up with a pre-approval study on existing data of a radiographic evaluation of the adjacent segment degeneration at pre-op and 24 months. There have been literature standards set for looking at adjacent segment degeneration as far as disc height, subluxation, facet changes and that sort of thing.

As I understand it, those are all on plain radiographs. You already have those at 24 months of

the index segment. I assume that means you have them of additional segments. And so, as such, that would be a pre-approval condition and I will stop with one, because when I go to two, it tends not to work.

CHAIRPERSON YASZEMSKI: Okay. That's fine. Do we have a second for this motion? I see no second, so this motion does not carry. Do we have additional conditions?

MS. MAHER: Can I make a comment?

CHAIRPERSON YASZEMSKI: Yes.

MS. MAHER: Can I suggest that somebody might move that the FDA and the sponsor go through all of these issues and discuss them and come up with ways to resolve them, as needed to be resolved, with using the FDA's scientific expertise?

CHAIRPERSON YASZEMSKI: I think we can suggest that. We also do though have to have the ability for everybody to make motions until they are exhausted. So noted. So noted.

UNIDENTIFIED SPEAKER: The motions or the people?

DR. KIRKPATRICK: Since you can't make a

motion or vote, let me propose that as a motion, that the FDA and the sponsor consider the remaining issues on what was provided to you by me with the exception of the ones that we have already voted on, and the exceptions of number 5, which I deleted, number 7, which seems to be answered already and number 10, which has been answered already. So that would actually cut down the number of things you have to look at.

CHAIRPERSON YASZEMSKI: So how about let's, if this is going to be your motion, say the ones that are included? Number one?

DR. KIRKPATRICK: Okay. Number 1 is included. Number 2 is included. Number 3 we have already voted down part of it and voted in the other part.

CHAIRPERSON YASZEMSKI: Okay.

DR. KIRKPATRICK: So 3 is excluded from this motion. Number 4 is included. Number 5 is excluded. Number 6 is included. Number 7 is excluded. Number 8 is included. Number 9 is included. Number 10 is excluded. Number 11 is

included. Number 12 has been voted down, so it is excluded, and number 13 has already been addressed.

CHAIRPERSON YASZEMSKI: Okay.

DR. KIRKPATRICK: So it's excluded.

CHAIRPERSON YASZEMSKI: So if I can repeat the motion, Dr. Kirkpatrick's motion for a condition is that on the conditions for approval that he circulated after his lead review, that the sponsor and FDA together consider numbers 1, 2, 4, 6, 8, 9 and 11 and arrive at resolution of those to the satisfaction of both. Is that your motion?

DR. KIRKPATRICK: That would be my motion.

CHAIRPERSON YASZEMSKI: Do I have a second?

DR. FINNEGAN: You have a second or a question? Can you not add 12 into this? That might solve your dilemma. I think that's what she was trying to do, was put 12 into this.

DR. KIRKPATRICK: 12 didn't get a second.

DR. FINNEGAN: Right, but if you put --

DR. KIRKPATRICK: So that's defeated in my mind, so it doesn't. I mean, they can consider

everything we say.

DR. FINNEGAN: Okay. All right.

CHAIRPERSON YASZEMSKI: Okay. Do we have a second?

DR. FINNEGAN: Yes.

CHAIRPERSON YASZEMSKI: Yes, a second. Any further discussion? We'll vote. Dr. Diaz?

DR. DIAZ: I agree.

CHAIRPERSON YASZEMSKI: Dr. Mabrey?

DR. MABREY: I agree.

CHAIRPERSON YASZEMSKI: Dr. Finnegan?

DR. FINNEGAN: I agree.

CHAIRPERSON YASZEMSKI: Dr. Kim?

DR. KIM: I agree.

CHAIRPERSON YASZEMSKI: Dr. Naidu?

DR. NAIDU: I agree.

CHAIRPERSON YASZEMSKI: Dr. Kirkpatrick?

DR. KIRKPATRICK: I agree and I'm very grateful for our colleague's suggestion.

CHAIRPERSON YASZEMSKI: Dr. Blumenstein.

DR. BLUMENSTEIN: I agree.

CHAIRPERSON YASZEMSKI: Dr. Besser?

DR. BESSER: Agree.

CHAIRPERSON YASZEMSKI: This motion passes.

MS. MAHER: Can I make one more comment on the motion even though it has passed, that the motion was not that they have to take all of these.

CHAIRPERSON YASZEMSKI: No.

MS. MAHER: But they are using their scientific rationale to determine.

DR. KIRKPATRICK: Exactly.

CHAIRPERSON YASZEMSKI: That they together mutually agree that these have been addressed, not that they take them all. We now have a motion for approval with conditions that has five conditions. Do we have any other conditions? Dr. Finnegan?

DR. FINNEGAN: Well, actually, Dr. Kim, go ahead.

CHAIRPERSON YASZEMSKI: Dr. Kim?

DR. KIM: Can I revisit the adjacent segment problem, because in thinking about it some more, I see no reason why we can't look at that with the continued assessment of the IDE and the continued

access patients. It's all part of the radiographic study. They looked at flexion-extension, but they could easily look at the adjacent segments.

CHAIRPERSON YASZEMSKI: And I think that I would submit that that's included. The FDA has heard that message and they can discuss whatever they want to discuss.

DR. KIM: Okay.

CHAIRPERSON YASZEMSKI: And that it will be accomplished without further additions to these conditions. Thank you. Additional conditions?

DR. FINNEGAN: You know, I can't leave without giving Dr. Witten at least a little bit of a heart attack. Because this is the first of its kind and because we are happier with efficacy than we are with safety, and that we think that safety has a longer term playtime, if you like, is it possible for us to ask that the company come up with a direct phone line for people to report adverse events for this particular device? I suspect this has never been done before, but for this --

CHAIRPERSON YASZEMSKI: If I could, may I

ask for commentary?

DR. FINNEGAN: Yes.

CHAIRPERSON YASZEMSKI: Both if Dr. Witten has a comment and I want to ask Dr. Christianson if he would comment or a member of his staff.

DR. WITTEN: Yes, actually I would suggest asking Dr. Christianson.

CHAIRPERSON YASZEMSKI: Mr. Christianson?

DR. WITTEN: To describe whatever their current mechanism would be first.

DR. FINNEGAN: Okay.

MR. CHRISTIANSON: First of all, thank you for promoting me to doctor. We already include in the package insert for our product an 800 number, so we have already got a mechanism for primarily physicians and hospital staff to call, and it sounds to me like one of our conditions of approval is some kind of tear-away card to give to the patients. We will be happy to put our 800 number on that, too, so that's very readily accomplished.

DR. MABREY: That could be on the registration card or whatever you pass out.

CHAIRPERSON YASZEMSKI: Dr. Blumenstein?

DR. BLUMENSTEIN: Did you just say to put it on the card that identified the device given to the patient?

DR. MABREY: No, I would just include that on the identification card that carries the lot number.

CHAIRPERSON YASZEMSKI: Yes.

DR. MABREY: And if the patient ever has a question about it, then they call your 800 number and there you go.

DR. BLUMENSTEIN: Okay. I was going to say that maybe on the back of that card you could have a signed -- a place for the surgeon to sign that they had undergone the training.

CHAIRPERSON YASZEMSKI: I'm just suggesting that we let FDA and the sponsor work that out.

DR. BLUMENSTEIN: No, the FDA doesn't have to --

UNIDENTIFIED SPEAKER: That wasn't a motion, was it?

CHAIRPERSON YASZEMSKI: No, that was not a motion. Do we have additional motions for conditions? Any? If not, any additional discussion? And if we don't, we're going to vote. Okay. We have a motion for approval with conditions. There are five conditions. A vote yes will be a vote for approval with all these five conditions needing to be accomplished. A vote no will be a vote for non-approval under these terms and if that happens to pass, we would need to get an alternate motion.

But here is the motion, approval with conditions. The first condition, that all currently enrolled patients in the continuous access group reach two years. The second, that follow-up occur and this is going to be in the form of a card that the patient would have with the identification number of the device, lot number and doctor, etcetera, as we have discussed. The third would be to study the motion of flexion and extension coupled to lateral bending for 10 million cycles and could be done after approval. The fourth would be training for surgeons, and the fifth would be the conditions circled on Dr.

Kirkpatrick's presentation sheet, numbers 1, 2, 4, 6, 8, 9 and 11.

I will ask for votes. Dr. Diaz?

DR. DIAZ: I agree.

CHAIRPERSON YASZEMSKI: Dr. Mabrey?

DR. MABREY: I agree.

CHAIRPERSON YASZEMSKI: Dr. Finnegan?

DR. FINNEGAN: I agree.

CHAIRPERSON YASZEMSKI: Dr. Kim?

DR. KIM: I agree.

CHAIRPERSON YASZEMSKI: Dr. Naidu?

DR. NAIDU: I agree.

CHAIRPERSON YASZEMSKI: Dr. Kirkpatrick?

DR. KIRKPATRICK: Yes.

CHAIRPERSON YASZEMSKI: Dr. Blumenstein?

DR. BLUMENSTEIN: Agree.

CHAIRPERSON YASZEMSKI: Dr. Besser?

DR. BESSER: Agree.

CHAIRPERSON YASZEMSKI: Thank you. This motion for approval with conditions passes.

UNIDENTIFIED SPEAKER: Are you going to go around and ask everyone the reason for their vote?

CHAIRPERSON YASZEMSKI: No, we're not quite done yet, folks. We're not quite done yet. I would like to go around, as a last thing, and go around the table and ask everybody to make any comments about the reasons for their vote. It was unanimous and we probably covered all these, but the FDA uses the information that we give them and they are very interested in the reasons why people voted. So you can be as brief as you want, but just mention anything that may not have been mentioned yet. Dr. Diaz?

DR. DIAZ: I voted the way I did, because I believe the company provided us with sufficient data to satisfy me that the safety and the effectiveness required by the FDA were, indeed, fulfilled and the recommendations for subsequent follow-up that were decided in the motion include any concerns that I may have had.

CHAIRPERSON YASZEMSKI: Thank you, Dr. Diaz. Dr. Mabrey?

DR. MABREY: Yes. First of all, I felt that the company went far and above what it had to do

to prove that this was a safe and effective device, number one. Number two, I would like to comment that I have never seen as detailed a rebuttal with 469 slides as I had as a high school debater. So I think this demonstrates that the company is thoroughly prepared. They have thoroughly researched it. They are very sincere about bringing this device safety to market, and I congratulate them on an excellent presentation.

CHAIRPERSON YASZEMSKI: Thank you, Dr. Mabrey. Dr. Finnegan?

DR. FINNEGAN: Yes, I concur. This was a brave new step and I agree. I think that I have less concerns about efficacy than I do about safety, and I hope that they will be diligent in guarding the safety, so that we don't have problems.

CHAIRPERSON YASZEMSKI: Thank you, Dr. Finnegan. Dr. Kim?

DR. KIM: This device represents a significant innovation in our strategy to treat a very challenging clinical problem, namely discogenic lower back pain. The sponsor has done a thorough job in

obtaining both preclinical and randomized control clinical trials. I think we all appreciate that a key question of implant longevity cannot be answered. Luckily, we do have some data from the European experience that helps us feel more comfortable with the fact that this is an efficacious and safe procedure, comparable to what exists today, namely the Anterior Interbody Fusion using the BAK cage.

CHAIRPERSON YASZEMSKI: Thanks, Dr. Kim.

DR. KIM: Given --

CHAIRPERSON YASZEMSKI: I'm sorry, Dr. Kim. Go ahead.

DR. KIM: Given that, that's the reason why I voted the way I did.

CHAIRPERSON YASZEMSKI: Thank you, Dr. Kim. Dr. Naidu?

DR. NAIDU: I voted to approve mainly because I think the sponsor has done an excellent job. They have presented a very vigorous PMA with excellent basic science and clinical follow-up. They have gone beyond what is required, I think, in showing the efficacy of the device, and that's why I approved it.

CHAIRPERSON YASZEMSKI: Thanks, Dr. Naidu. Dr. Kirkpatrick?

DR. KIRKPATRICK: I agree with the sponsor that we don't know all the issues related to the cause of back pain, and this is an empirical measure to try and solve that problem. I agree that it is reasonably safe and efficacious within the limits of what was studied, and I believe that the motion, as approved, was a reasonable compromise of the need for long-term follow-up for both the safety and effectiveness measure, as well as the need to put innovation on the market.

CHAIRPERSON YASZEMSKI: Thanks very much, Dr. Kirkpatrick, and thank you for your primary review of this application. Dr. Blumenstein?

DR. BLUMENSTEIN: Yes. I think the company did a better than average clinical trial and the canonical analysis was adequate to show non-inferiority. The sensitivity analyses gives me confidence that the primary analyses are valid, and the conditions for long-term follow-up satisfy me as to the concerns I have about safety.

CHAIRPERSON YASZEMSKI: Thanks, Dr. Blumenstein. Dr. Besser?

DR. BESSER: With the conditions for follow-up, I believe the company has presented its case and that this device will be a benefit for those receiving it.

CHAIRPERSON YASZEMSKI: Thank you, Dr. Besser. Ms. Maher, I would like to ask for your comments.

MS. MAHER: I think that the company did do an excellent job in the clinical study. Actually, it's better than better than average, and I think that as a Panel we have done a good job at looking at all the issues and trying to take the best case of least burdensome approach to getting --

CHAIRPERSON YASZEMSKI: Thank you, Ms. Maher. Ms. Luckner?

MS. LUCKNER: I think the company has discharged their duty to bring to the FDA Panel a product that meets the FDA definition of safe and effective. I think I am totally impressed with the sponsor's response to all the Panel questions, that

they were totally prepared for all the issues that were presented. Very well done. And finally, I believe the Panel and the FDA discharged their duty to protect the public and balance promoting innovation.

CHAIRPERSON YASZEMSKI: Thanks very much, Ms. Luckner. Let me do two final things. I would like to thank all the Panel Members for their preparation and participation today, including and especially our consumer and industry reps. I would like to ask Dr. Witten if she has any comments from the FDA's perspective?

DR. WITTEN: No. I would like to thank the Members of the Panel for participating today, to the FDA review team and the sponsor also for their presentations.

CHAIRPERSON YASZEMSKI: Thanks, Dr. Witten. I would like to also end with saying the sponsor has heard from the Panel congratulations about the thoroughness of their presentation, and I would like to add my thanks to them for a very thorough presentation today. And with that, we adjourn this meeting.

(Applause)

(Whereupon, the meeting was concluded at 5:22 p.m.)

CERTIFICATE

This is to certify that the foregoing transcript in the matter of: Orthopedic and Rehabilitation Devices Panel

Before: DHHS/PHS/FDA/CDRH

Date: June 2, 2004

Place: Gaithersburg, MD

represents the full and complete proceedings of the aforementioned matter, as reported and reduced to typewriting.